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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Murray Goodman

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

02/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,130	Applicant(s) GOODMAN ET AL.	
	Examiner DAVID LUKTON	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/11/05, 2/10/06, 2/6/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicants' election of Group 5 (claims 9-11) is acknowledged, as is the elected specie (the compound of claim 11).

Claims 9-11 are examined in this Office action; claims 1-8 and 12 are withdrawn

△

Objection is raised to claim 9; in the view of the examiner, clarity could be enhanced somewhat by defining a variable (such as "X"), and then referring to that variable in the latter part of the claim, as follows:

A dendrimer comprising (a) a disulfide bond, (b) at least two branch groups, and (c) two or more "X" groups,

wherein each "X" group is selected from the group consisting of a guanidine group, a protonated guanidine group, a protected guanidine group; an amidine group, a protonated amidine group, a protected amidine group; a ureido group, a protonated ureido group, a protected ureido group; a thioureido group, a protected thioureido group, and a protonated thioureido group;

and wherein at least two of the two or more X groups are borne at the end of the at least two branch groups of the dendrimer.

△

The following is a quotation of 35 USC, §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 9 is rejected under 35 U.S.C. §103 as being unpatentable over Klimash (USP 6,020,457).

Klimash discloses (col 28, line 13-16) reaction of a “PAMAM” dendrimer with iminothiolane, producing a thiol-bearing dendrimer bearing 17 sulfhydryls per dendrimer. The thiol-bearing dendrimer was then subject (col 28, lines 45-49) to oxidation, producing disulfide bonds.

As applicants may be aware, iminothiolane reacts with amines to produce a compound which contains both an amidino group, and a thiol group, represented as follows:



Thus, if one begins with a dendrimer (which contains branching groups) and reacts it with iminothiolane, the result is a sulfhydryl-bearing, branched dendrimer that contains amidino groups. If the sulfhydryl group is oxidized to a disulfide, the requirements of the claims are met.

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Alternatively, the sulfhydryl-bearing dendrimer can be reacted with a biologically active molecule (BAM) such that a disulfide linkage exists between the dendrimer and the BAM. Such disulfide linkages are of interest, in part, because of the facile release of the BAM *in vivo*.

Thus, the claim is rendered obvious.

▲

Claim 9 is rejected under 35 U.S.C. § 103 as being unpatentable over Maignan (USP 6395867).

Maignan discloses reaction of dendrimers with iminothiolane. As indicated above, (the 103 over Klimash) the result is a dendrimer that contains both amidino and thiol groups. Also disclosed (col 8, line 20) is that the compounds can serve as antioxidants. As applicants may appreciate, in order for an antioxidant to be effective, it has to become oxidized to some degree (which an oxidant is present). Thus, it would have been obvious that the thiol groups will form disulfide bonds. The existence of disulfide bonds is also explicitly cited at col 8, line 43.

Thus, the claim is rendered obvious.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654